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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/129,298	08/05/98	ARNTZEN C	7991-023-999

HM12/0802

KIMERAGEN INC
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EXAMINER	
ZAGHMOUT,O	
ART UNIT	**PAPER NUMBER**
1649	7

DATE MAILED: 08/02/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/129,298	Arntzen et al.
Examiner	**Group Art Unit**
Ousama Zaghmout	1649

☒ Responsive to communication(s) filed on *Jul 16, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-72* is/are pending in the application.

Of the above, claim(s) *5-7 and 28-72* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4 and 8-27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED OFFICE ACTION

Claims 1-72 are pending.

Applicant's election without traverse of group I, claims 1-4, 8-30, and 50-53 in Paper No. 5 is acknowledged.

After a further consideration of the record and the elected claims, The Examiner has decided that the claims are in fact made up of three independent and patentability distinct inventions even though the subject matter is related. As such, searches of all of these inventions will be a burden on the Examiner. Therefore, the Examiner has restricted these claims into three groupings: Group I, claims 1-4, 8-27 which are drawn to a method of making localized mutation in a target gene in any part of the plant where intact cells are used in the transformation process, classified in class 435, subclass 238; Group V, claims 28-29 which are drawn to a method of making localized mutation in a target gene that is present only in the plastid where intact cells derived from the plastid are used in the transformation process, classified in class 435, subclass 238; Group VI, claims 50-53 are drawn to a method of making localized mutation in a target gene in any part of the plant where protoplasts instead of intact cells are used in the transformation process, classified in class 435, subclass 238. The invention of group I does not require the plastid specific promoter as in group V or the use of protoplasts as in group VI. Clearly, these inventions are independent since you could practice one invention without practicing or infringing any of the others. Similarly, each is patentability distinct since they constitute different products which can each support its own

patent. Other groupings II-IV which were mentioned in the previous Office Action are still intact.

In a phone conversation with the Mr. Daniel Hansburg on 7-23-1999, the Examiner has informed the Applicants' representative of the of the new restriction requirements as specified above. Mr. Hansburg has elected group I, claims 1-4, 8-27 with traverse (please see the attached interview summary). A confirmation of this election by the Applicants is respectfully requested. Therefore, claims 1-4, 8-27 were examined on the merit in this Office Action. Claims 5-7, 28-72 were withdrawn from further consideration as they are drawn into non-elected inventions.

Claim Rejections - 35 USC § 112

Ist. Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for making a localized mutation in the gene which encodes the selectable marker ALS1 and ALS2, and in the gene which encodes the

scorable marker GFP using the recombinagenic oligonucleobase, does not reasonably provide enablement for making the localized mutation in a non-selectable or non-scorable genes or other genes of plant origins.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants have disclosed in the specification a method for making a localized mutation in the gene which encodes the selectable marker ALS1 and ALS2, and in the gene which encodes the scorable marker GFP using the recombinagenic oligonucleobase. However, Applicants claims are not limited to the scope encompassed by the exemplified subject matter. Instead, Applicants broadly claim a method for making a localized mutation in any gene of plant origin using the recombinagenic oligonucleobase. Applicants have exemplified in the specification 2 examples where the selection of transgenic plant that expressed a gene whereby localized a mutation can be easily screened and identified. Applicants have not disclosed other examples whereby genes of plant origin or genes which do not show visible phenotype upon the expression of a transgene which contains a localized mutation as claimed in the method of this application. As not all localized mutation are likely to cause a change in the phenotype of the transgenic plant cell, the question is whether a person with skill in the art will be able to identify transgenic cell containing the localized mutation in the absence of any morphological, physiological or biochemical indication. A genomic Southern blot analysis of the

total genomic DNA from transgenic plant cell will tell a person with skill in the art that the inserted gene is in but it does not tell if the localized mutation is present in the target gene. Applicants have not taught a person with skill in the art of the criteria that a person with skill in the art should use in identifying the nucleotide sequences to be used in selecting the nucleotide sequences which make up the recombinagenic oligonucleobase. This is important in the light of the fact that minor localized mutation in certain part of a nucleotide sequence might not render a protein ~~to~~ cause a change in the phenotype of the transgenic plant cell.

Applicants have failed to address many of these important issues which are essential for the enablement of the invention as claimed in the instant application. Applicants have provided no specific guidance as to how to select the nucleotide sequences which will produce a protein or a polypeptide conferring the desired effect. The specification is silent as to the criteria used to identify transgenic plant cells which express the localized mutation. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not. Hence, due to the lack of any working examples of the inventions, and the inability of one skilled in the art to predict which if any of all possible nucleic acid molecules which will be useful in the manner suggested, and the unpredictability of the field, it would require undue experimentation to practice the claims.

In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner's position that one skilled in the

art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations.

Conclusion

No claims are allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, L. Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

July 26, 1999

L. F. Smith

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